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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Naohisa Kawamura

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EXAMINER

WESTERBERG, NISSA M

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1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,751	Applicant(s) KAWAMURA ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 26 is/are pending in the application.
- 4a) Of the above claim(s) 6, 19, 23 - 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 5, 7 - 18, 20 - 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 23 – 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected copolymer, there being no allowable generic or linking claim. Applicant timely traversed the election requirement in the reply filed on June 30, 2008. Applicant was required to elect the monomers which comprise the copolymer. The monomer combination in new claims 23 – 26 is not the elected species and therefore these claims are withdrawn from further consideration.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

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USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 8 – 18 and 20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 8 of copending Application No. 10/585168. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

Applicants will address this rejection by the filing of a terminal disclaimer in the later-allowed application or by claim amendments in the event that the instant claims are allowed.

Therefore, this rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008.

4. Claims 8 – 15, 17, 18 and 20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 3, 7 and 8 of copending Application No. 11/792265. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

Applicants will address this rejection by the filing of a terminal disclaimer in the later-allowed application or by claim amendments in the event that the instant claims are allowed.

Therefore, this rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 5 and 7 were rejected under 35 U.S.C. 102(b) as being anticipated by Knutson et al. (US 5,435,879). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Knutson fails to disclose an adhesive comprised of a copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and one or more monomers selected from the group consisting of other (meth)acrylic monomers with no acetoacetyl group and copolymerizable vinyl monomers in a “medicinal tape preparation for percutaneous absorption”. Conditions not disclosed by Knutson et al. in order for the polymer to be used as an adhesive include 1) a medicament dissolved in the polymer at a suitable concentration; 2) the medicament must release from the polymer to the user’s skin; 3) the polymer should have no irritation to the skin; 4) the polymer must have suitable adhesive strength and adhesive strength; and 5) the polymer must have compatibility with oily substances such as drug-dissolving agents. Knutson fails to disclose a copolymer suitable for a medicinal tape preparation, which generally contain oily substances as drug-dissolving agents, percutaneous absorption accelerators and plasticizers. There would be no need to admix oily substances to adhere to any of the materials disclosed by Knutson such as plastics, woods, ceramics, etc. Knutson fails to disclose or suggest a polymer having good adhesiveness to human skin and good release profile for the drug to be absorbed percutaneously. For example, the mechanical strength measured by Knutson fails to provide any suggestion whether the polymer adhesive could be an adhesive for a medicament and the adhesives are applied to flat metal plates, plastics and the like as oppose to the uneven surface of “live” skin.

These arguments are not persuasive. As previously indicated, “for a medicinal tape preparation for percutaneous absorption” is a recitation of intended use. Knutson et al. described a copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and a (meth)acrylic monomer with no acetoacetyl group. The instant claims recite a copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and a (meth)acrylic monomer with no acetoacetyl group. Therefore, the polymers described by Knutson et al. must be suitable for a medicinal tape preparation for percutaneous absorption as both the instant claims and Knutson et al. describe a copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and a (meth)acrylic monomer with no acetoacetyl group. Similarly, the polymers of Knutson et al. must have good adhesiveness to human skin and good release profile for the drug to be absorbed percutaneously as the copolymers of the instant claims and those disclosed by Knutson are a copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and a (meth)acrylic monomer with no acetoacetyl group.

Applicants arguments that the materials of Knutson et al. are unsuitable for the intended use are provided without factual support and therefore are mere allegations which are not found to be persuasive. Same compositions must be capable of performing the same intended use.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a medicament dissolved in the polymer, the presence of oily substances as drug-

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dissolving agents, percutaneous absorption accelerators and plasticizers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In regards to the application of the adhesive to skin versus flat materials disclosed by Knutson et al., the adhesive is applied to a backing which is then designed to adhere to another surface or article (col 13, ln 14 – 16). As described in the test example 1 of the instant specification, the adhesive polymer composition is applied to a flat support material such as polyester film (¶¶ [0064] – [0065]), which is the same process disclosed by Knutson et al. Additionally, application to “live” human skin, if such a limitations was present in the claims, which it is not, would be a recitation of intended use. As the same materials are described in both the instant claims and Knutson et al., the polymers of Knutson et al. are capable of meeting this limitation.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 – 5, 7 – 18 and 20 – 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wick (US 4,751,087) in view of Knutson et al. (US 5,345,879). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 9, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Wick completely fails to suggest an adhesive made of “a copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and a (meth)acrylic monomer with

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no acetoacetyl group or a copolymerizable vinyl monomer". The combination of monomers is critical for performance of the adhesive as a medicinal tape preparation. Knutson, described in greater above, fails to disclose or suggest a copolymer used for a medicinal tape for percutaneous absorption. Thus, absent hindsight, a person of ordinary skill in the art would not have combined Wick so as to derive the features in a medicinal tape in the instant claims.

These arguments are not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Wick and Knutson et al. both disclose pressure sensitive adhesives that are applied to a substrate for the purpose of adhering to another surface or article. The failure of Knutson to explicitly disclose the intended use limitation of "for a medicinal tape preparation for percutaneous absorption" has been discussed in greater detail

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above. One of ordinary skill in the art would be motivated to use the copolymer obtained by copolymerization of a (meth)acrylic monomer having an acetoacetyl group and a (meth)acrylic monomer with no acetoacetyl group in the device of Wick because of improved cohesive strength without the incorporation of crosslinking monomers with no little or no detriment to adhesive tack or adhesion (abstract of Knutson et al.). Therefore this rejection is maintained.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. This application contains claims 6, 19 and 23 – 26 drawn to an invention nonelected with traverse in the reply filed on June 30, 2008. A complete reply to the

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final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW